

AUG -1 2008

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**  
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

**1. Identifying Information:**

**Submitter:** Medtronic Vascular  
37A Cherry Hill Drive  
Danvers, MA 01923

**Contact Person:** Colleen Mullins  
Sr. Regulatory Affairs Specialist  
(978) 739-3267

**2. Classification Name:** Device, Coronary Saphenous Vein Bypass Graft,  
Temporary, For Embolization Protection (21 CFR Part 870.1250) Product Code  
NFA

**3. Proprietary Name:** Interceptor® PLUS Coronary Filter System

**4. Name of Predicate Devices:**

|  |         |
|--|---------|
| FilterWire EZ™ Embolic Protection System (2.25mm-3.5mm)        | K061332 |
| FilterWire EZ™ Embolic Protection System                       | K052280 |
| SpiderFX™ Embolic Protection Device                            | K063785 |
| PercuSurge GuardWire Temporary Occlusion and Aspiration System | K013913 |
| GuardWire 3-6 Temporary Occlusion and Aspiration System        | K023878 |

**5. Description:**

The Interceptor® PLUS Coronary Filter System (the Device) consists of six components; an 180cm extendable Steerable Vascular Filter, an Actuator Handle, a Torque Handle, a Guidewire Introducer, Peel Away Introducer and a RX Facilitator Catheter. The Steerable Vascular Filter is comprised of a radiopaque nitinol filter mounted near the distal tip of a steerable 0.014 inch nitinol hypotube guidewire. The guidewire extends 3.5cm beyond the distal end of the filter in the collapsed state to facilitate distal tracking and steering through tortuous vessels and tight lesions. The proximal end of the steerable vascular filter contains four large openings (Approximately 1400 microns for the 3.5mm filter, >1500 microns for the 4.5mm filter size and >1800 microns for the 5.5mm filter size) that allow embolic particulate to enter the filter.

In addition to the Interceptor® PLUS Coronary Filter System, there is an optional Angled RX Facilitator Catheter when an alternative tip configuration is desired for filter withdrawal.

**6. Intended-Use:**

The Interceptor® PLUS Coronary Filter System is intended for use in saphenous vein bypass grafts, with a reference vessel diameter between 2.5 mm and 5.25mm, in conjunction with percutaneous transluminal coronary intervention (PTCI) for embolic particulate capture. The Interceptor® PLUS Coronary Filter System is intended for temporary use in conjunction with other therapeutic devices and is intended to be removed at the completion of the interventional procedure.

**7. Summary Of Substantial Equivalence:**

The Interceptor® PLUS Coronary Filter System for use in saphenous vein bypass grafts, is equivalent to the following predicate devices in that the intended use, principles of operation, design and materials are similar:

|  |         |
|--|---------|
| FilterWire EZ™ Embolic Protection System (2.25mm-3.5mm)        | K061332 |
| FilterWire EZ™ Embolic Protection System                       | K052280 |
| SpiderFX™ Embolic Protection Device                            | K063785 |
| PercuSurge GuardWire Temporary Occlusion and Aspiration System | K013913 |
| GuardWire 3-6 Temporary Occlusion and Aspiration System        | K023878 |

**8. Summary of Safety and Performance:**

A Clinical evaluation, AMEthyst study, was conducted in a randomized clinical trial involving a total of 800 saphenous vein graft patients. Patients were enrolled and randomized to one of two groups (Treatment [Interceptor or Interceptor PLUS Coronary Filter System] or the Control [GuardWire® Temporary Occlusion Balloon and Aspiration System or FilterWire EZ™ Embolic Protection System]) at an unbalanced 2:1 ratio. The primary endpoint of this trial was Major Adverse Cardiac Events (MACE) related to the target vessel at 30 days: defined as death, Q-wave or non-Q wave MI, emergent coronary artery bypass surgery, or target vessel revascularization within 30 days of the index procedure. The primary endpoint analysis resulted in a MACE rate of 8.0% (40/501) in the Treatment arm and 7.3% (18/247) in the Control arm which demonstrates non-inferiority when tested to a delta of 4.5%. The upper 95% confidence interval of the difference between the two groups was 4.0%.

Note: During the conduct of the AMEthyst study there were 163 Treatment (Interceptor and Interceptor PLUS) patients and 82 Control (GuardWire and FilterWire) patients who had at least one missing CK-MB result. To address this issue of missing CK-MB data an additional analysis on MACE was performed to determine a statistical estimate regarding the number of patients who may have experienced a non-Q wave MI. For the purposes of the analysis Interceptor subjects were excluded from the Treatment group and only Interceptor PLUS subjects were analyzed resulting in 139 patients. The number of Control patients remained 82. Data from 158 patients in the GuardWire arm of the SAFER study and 178 patients in the Control arm from the Amethyst study with non-missing CK-MB at all three time points (6-8, 12-16, and 18-24) were used in conjunction with conditional probability theory to estimate the number of non-Q wave MI that could have resulted for each of the various missing data patterns. The probabilities of a non-Q Wave MI for the Interceptor PLUS arm was based on the probabilities calculated for the SAFER study. The probabilities of this event in the Control arm were based on the Control Arm of the Amethyst study. For the Interceptor PLUS group, the total expected number of additional patients with non-Q wave MI was 2.392. For the Control group, the total expected number of additional patients with non-Q wave MI was 2.077. Taking a conservative approach and assuming 3 additional Interceptor PLUS patients experienced 30-day MACE, versus only 2 in the control group, the rate of MACE at 30 days would increase from 8.4% to 9.1% for Interceptor PLUS arm and from 7.3% to 8.1% for the Control arm. The resulting non-inferiority p-value on the Interceptor PLUS vs. Control risk difference, using an absolute non-inferiority margin of 4.5%, is 0.050, allowing non-inferiority of Interceptor Plus to Control to be claimed.

Based on acute procedural and 30-day clinical results, the Interceptor PLUS Coronary Filter System has demonstrated non-inferior safety and efficacy compared with the GuardWire Temporary Occlusion Balloon and Aspiration System and the FilterWire EZ Embolic Protection System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 1 2008

Medtronic Vascular  
c/o Ms. Colleen Mullins  
Senior Regulatory Affairs Specialist  
37 A Cherry Hill Drive  
Danvers, MA 01923

Re: K073523

Trade/Device Name: Interceptor® PLUS Coronary Filter System  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: NFA

Dated: June 30, 2008

Received: July 1, 2008

Dear Ms. Mullins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

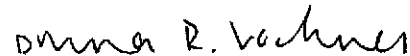
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality


systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K073523

Device Name: Interceptor® PLUS Coronary Filter System

### Indications for Use:

The Medtronic Interceptor® PLUS Coronary Filter System is intended for use in saphenous vein bypass grafts, with a reference vessel diameter between 2.5 mm and 5.25mm, in conjunction with percutaneous transluminal coronary intervention (PTCI) for embolic particulate capture. The Interceptor® PLUS Coronary Filter System is intended for temporary use in conjunction with other therapeutic devices and is intended to be removed at the completion of the interventional procedure.

The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid, or peripheral vasculature

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Dan R. Vachon*  
(Division Sign-Off)  
Division of Cardiovascular Devices

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